

INVENTOR: McBride et al
TITLE: Internet Device Operation for Medical Testing

attorney docket: CARDIOBEAT-3

REMARKS

Claims 1 through 12 are in the application as filed.

Claims 1-12 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent 6,162,180 (Meisel et al) in view of U.S. Provisional Application for Patent 60/107,707 (Maus et al).

The primary reference relied on by the Examiner has been misread and misapplied by the Examiner.

Claim 1 recites, inter alia: "downloading via the Internet a medical testing program from a server, said medical testing program being utilized to provide non-invasive cardiovascular function related test measurement data;

coupling at least one non-invasive sensor to said Internet device, said at least one sensor being non-invasively coupled to and disposed on a patient to obtain impedance test measurement data"

The Examiner in an attempt to meet the language of Applicant's claimed invention states that Meisel teaches "a medical testing program being utilized to provide non-invasive cardiovascular function (column 1, lines 58-60)" and "coupling at least one non-invasive sensor to the Internet device, the at least one sensor being non-invasively coupled to and disposed on a patient to obtain impedance test measurement data (column 1, lines 58-60; column 2, lines 3-17)"

At no place does Meisel show, teach or suggest the use of a sensor that is non-invasively coupled to a patient. To the contrary, Meisel utilizes implanted sensors. The "non-invasive" aspect of Meisel utilizes invasive sensors that are implanted in the patients body. When Meisel refers to invasiveness, Meisel refers to the drawing of blood from the right ventricle of the patient's heart to determine oxygen saturation. (See col. 1, lines 14-23).

The "non-invasive" aspect of the system of Meisel pertains to the fact that a sensor is and must be invasively implanted in the heart. Only after the sensor is implanted in the heart and left in place, is the system "non-invasive". This is made particularly clear in the second paragraph of the Summary of the Invention wherein Meisel clearly states:

A non-invasive cardiac monitoring system in accordance with the principles of the present invention utilizes an implantable medical device previously implanted in a human body which is coupled to an oxygen sensor situated in the heart."

From this description alone, it is clear that the "non-invasive" aspect of Meisel has nothing at all to do with whether an invasive sensor is utilized. The "non-invasive" aspect of the

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"system" requires an invasive sensor to be implanted in the heart of the patient. The Meisel patent is replete with references to the sensor being implanted in the body of the patient, and is also shown in FIG.1 as sensor 17. Rather than pointing to each and every occurrence in Meisel where it is made clear that the invasive sensors are utilized, the Examiner is invited to reread the reference.

Based on the foregoing alone, Applicant's invention is not shown, taught or even remotely suggested by Meisel. In fact, Meisel teaches away from Applicants use of non-invasive sensors as recited in the claims.

In addition, contrary to the Examiner's contention at page 2 that Meisel teaches obtaining "impedance test measurement data" Meisel does not even utilize the term "impedance". It is respectfully submitted that the Examiner has misread Meisel. As pointed out in Applicant's specification, impedance test measurement data results from specific impedance measuring. Impedance is an electrical quantity that is a measure of the resistance/capacitance/inductance along a conductive path. The oxygen sensor of Meisel provides "venous oxygen saturation data". It does not provide impedance test measurement data. Meisel is absolutely silent on impedance test measurement.

On this additional basis Applicant's claimed invention is not shown, taught or suggested by Meisel

It is noted that the Examiner's comments at the first full paragraph of page 3 do not make any sense beyond the statement that "Meisel et al do not explicitly teach the downloading of a medical testing program via the Internet from a server."

The Examiner points to Maus et al as teaching the downloading of a medical testing program via the Internet from a server." The Examiner states that it would be obvious to modify Meisel by downloading medical testing programs so that patients may upload programs.

However, there is no suggestion in Meisel that downloading of programs is even considered. There is no indication in the Examiner's suggestion as to why one skilled in the art would modify Meisel as suggested by the Examiner.

In addition, the Examiner at page 4, states that Meisel does not teach utilizing a trending algorithm on the history. The Examiner points to Maus as utilizing a trending algorithm and points to page 5, line 27 to page 6, line 6. However, the Examiner misstates what the teachings of Maus are. Maus is silent on utilizing any trending algorithms and merely states that a "report may include a trend analysis showing how cholesterol, blood glucose, and weight levels have changed over multiple readings." The passage pointed to by the Examiner does not suggest the use of trending algorithms.

The passage pointed to does not suggest the use of trending algorithms to "maintaining a history of test measurement data and cardiac function test data for said patient" and "utilizing a

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trending algorithm on said history to develop a medical condition trend for said patient" as recited in claim 1.

It is respectfully submitted that the Examiner is not following the examination standards for determination of obviousness.

The Examiner's attention is drawn, in particular, to MPEP 706.02(j) and MPEP 2143 and the three basic criteria that must be set out to establish a prima facie case of obviousness.

The first criteria is that "there must be some suggestion of motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings."

"Second, there must be a reasonable expectation of success."

"Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicants disclosure." MPEP 2143 quoting *In re Tack*

MPEP 706.02(j) quotes *Ex Parte Clapp*: "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention, or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to be obvious in light of the teachings of the references."

MPEP 2143.01 clearly points out that the "level of skill in the art cannot be relied upon to provide the suggestion to combine references" *Al-Site Corp. v. ISI Int'l Inc.*

MPEP 2143.01 further provides the clear guidance that: "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references." citing *Ex parte Levengood*

MPEP 2143.01 further clearly provides the guidance that the proposed modification of the prior art cannot change the principle of operation of the prior art reference.

The Examiner's attention is also directed to MPEP 2144.03 which clearly sets forth the standards, in accordance with *In re Zurko* and the other cases cited therein, for reliance on "well known" prior art. The Examiner's attention in particular is directed to 2144.03 C wherein "If

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applicant challenges a factual assertion as not properly officially noticed or not properly based upon common knowledge, the Examiner must support the finding with adequate evidence."

There is no suggestion in either of the references applied to claim 1 that they may be combined as suggested by the Examiner.

For the reasons set forth above, claim 1 is not shown, taught or made obvious by the references taken singly or in combination.

The remaining claims all depend from claim 1 and add further limitations. Accordingly, the remaining claims are likewise not shown, taught or made obvious by the references taken singly or in combination.

With respect to claims 2 and 3, the Examiner without any basis suggests that it would be obvious to "include an instructional guide in the device." None of the references suggests that. The Examiner points to a passage in Meisel in which a label affixed to a device includes operation instructions. It is submitted that such a teaching does not lead to the modification suggested by the Examiner. It is requested that the Examiner provide adequate evidence to support the Examiner's assertion.

For this additional reason claims 2 and 3 are not shown, taught or made obvious by the references taken singly or in combination.

With respect to claims 4 and 5, it is believed that the Examiner intended the basis for the rejection to be Meisel in view of Maus. However, the Examiner mistakenly points to page 6 – page 7 of Maus as showing executing a data verification program. In fact, what is discussed by Maus is the use of a standard test strip not a data verification program.

For this additional reason, claims 4 and 5 are not shown, taught or made obvious by the references taken singly or in combination.

With respect to claim 6, the Examiner notes that neither reference teaches "uninstalling the medical testing program..." However, the Examiner without pointing to any basis in either reference for doing so, states that one of ordinary skill in the art would include the uninstalling feature. It is respectfully submitted that there is no basis for the conclusion that the Examiner reaches and that there is no apparent reason for modifying the teachings of the references as the Examiner suggests. It is requested that the Examiner provide adequate evidence to support the Examiner's assertion.

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In addition, the Examiner's rejections of claims 10 and 12 rely upon teachings in the references of the use of impedance testing. However, the Examiner's rejections are not well founded since the references are absolutely silent on impedance testing.

It is clear that the Examiner has not properly read or applied the references. The primary reference does not utilize non-invasive sensors, but expressly teaches the use of implanted sensors. Neither reference teaches the use of impedance measurement testing.

Accordingly, none of the claims in the application are shown, taught or made obvious by the references.

Once again, the Examiner is reminded that prosecution of this application has, to date, been piecemeal. Piecemeal prosecution is expressly prohibited by the M.P.E.P. In addition, the Examiner is reminded that it must be assumed that the Examiner's examination of the application is complete. Since no amendments are made to the claims, no new basis for rejection is presented. Applicant is entitled to rely upon the Examiner's search as being complete.

None of the claims in the application are shown, taught or made obvious by any of the references of record taken singly or in any combination.

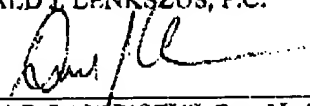
It is respectfully submitted that the claims in the application are patentably distinct from all the references that have been cited or applied by the Examiner. At this time, it is respectfully submitted that further prosecution on the merits is no longer necessary nor required. It is specifically requested that the Examiner withdraw the rejections.

In view of the foregoing comments, it is believed that all the claims presently in the application are in condition for allowance. Reexamination and reconsideration are requested. It is further requested that

the claims be allowed and that this application be passed to issue. An early notice of allowance would be appreciated.

Respectfully submitted,
DONALD J. LENKSZUS, P.C.

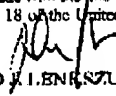
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